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D-1595F) 7590 05/19/2003	RMATION NO.	ATTORNEY DOCKET NO.	FIRST NAMED INVENTOR	FILING DATE	APPLICATION NO.	
Michael I. Call	1149	•	Francis Barany	09/26/2001	09/963,920	
Michael I. Goldman	•			05/19/2003	759	
EATHARIER .		EXAMINE				
NIXON PEABODY LLP Clinton Square P.O. Box 31051	SHRI	PONNALURI, PA		DY LLP	Clinton Square	
	ER NUMBER	ART UNIT		4603		
1639	<u> </u>	1639			,	
DATE MAILED: 05/19/2003	>	DATE MAILED: 05/19/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/963,920 Applicant(s)

Examiner

Art Unit

Barany et al



Padmashri Ponnaluri 1639 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. . If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on _____ 2a) This action is **FINAL**. 2b) X This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 1-147 is/are pending in the application. 4a) Of the above, claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) 🗌 Claim(s) is/are objected to. 8) 💢 Claims 1-147 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) \square The proposed drawing correction filed on is: a) \square approved b) \square disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. $3. \square$ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) U The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

6) Other:





DETAILED ACTION

1. Claims 1-147 are currently pending in this application.

Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner at andrew.wang@uspto.gov or 7(703)306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - 1. Claims 1-6, 11, 13 and 35-88, drawn to a method for identifying one or more of a plurality of sequences differing by one or more single based changes, insertions, deletions, or translations in a plurality of target nucleic acids, classified in class 435, subclass 6.
 - II. Claims 7-10, drawn to a method of identifying one or more plurality of sequences, wherein the sample contains unknown amounts of target nucleotide sequences, and





- providing a known amount of one or more marker target nucleotide sequences, classified in class 435, subclass 6.
- Ш. Claims 12, drawn to a method for identifying one or more plurality of sequences, in which the oligonucleotide probes have target specific portions which overlap, classified in class 435, subclass 6.
- IV. Claims 14-19, drawn to a method for identifying one or more plurality of sequences, the probes of the first set, the probes in the second group have common target specific portion, and the probes in the first group have differing target specific portion, classified in class 435, subclass 6.
- V. Claims 20-21 drawn to a method of detecting low abundance of multiple allele differences, wherein one or more sets of oligonucleotide probes in a group share common oligonucleotide probes, and the first oligonucleotide probes have different target specific portion, classified in class 435, subclass 6.
- VI. Claims 22-23, drawn to a method of detecting low abundance of multiple allele differences, by providing a known amount of one or more marker target nucleic sequences, classified in class 435, subclass 6.
- VII. Claims 24-26, drawn to a method of detecting multiple allele differences at one or more nucleotide positions in a single target nucleotide sequences, wherein the first oligonucleotide probes have a common target specific portion and the second





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oligonucleotide probes have differing target-specific portions, classified in class 435, subclass 6.

- VIII. Claims 28-34, drawn to a method of detecting multiple allele differences at one or more nucleotide positions in a single target nucleotide sequences, wherein the second oligonucleotide probes have a common target specific portion or the first oligonucleotides have a common target specific portion, classified in class 435, subclass 6.
- IX. Claims 89-112, drawn to, classified in class 436, subclass 518.
- X. Claims 113-119, drawn to, classified in class 435, subclass 6.
- XI. Claims 120-137, drawn to an array of oligonucleotides on a solid support, classified in class 536, subclass 23.1.
- XII. Claim 138-147, drawn to a kit for identifying one or more of a plurality of sequences differing by a single base changes, classified in class 435, subclass.
- 3. The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I to XI are drawn to a method which differs from each other the use of different probes, and the groups are distinct from each other. The different method groups are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects and different reactants.

Inventions of group XII are draw to a kit which can be used with any of the method groups I to XI. The inventions can be shown to be distinct if either or both of the following can be



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shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group XII is used with several different groups, restriction between the groups is proper.

- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undo search burden, and restriction for examination purposes as indicated is proper.
- 6. This application contains claims directed to the following patentably distinct species of the claimed invention:

Applicants are requested to elect the following:

a) applicants are requested to elect one from 'single-base changes, deletions, insertions, or translocation'



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- b) detectable reporter label;
- c) marker target nucleotide sequence;
- d) a specific ligase;
- e) the sequence of first oligonucleotide probe set;
- f) the sequence of the second oligonucleotide probe set;
- g) the oligonucleotide length of the probes;
- h) the length of the target specific portion of the probes;
- 1) a specific carrier DNA;
- j) a specific polymerase based amplifying procedure;
- k) specific oligonucleotide probe sets;
- 1) one specific disease being detected;
- m) a specific genetic disease;
- n) a single agent of the infectious disease;
- o) specific solid support;
- p) the form of the solid support;
- q) functionalization of the solid support;
- r) if the solid support is functionalized with amino group the reaction of amino group is selected from...;
- S) if the solid support is functionalized with olefin containing silane, one specific olefine containing silane;





t) if olefin containing monomer is used for functionalizing the solid support, applicants are requested to elect a single group of olefine containing monomer;

- u) one specific method of scanning;
- v) specific capture ligand.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(1).

9. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri Primary Examiner Technology Center 1600 Art Unit 1639 19 May 2003

ADMASHRI PONNALURI PRIMARY EXAMINER



DATE:

RESTRICTION ELECTION FACSIMILE TRANSMISSION

FROM/ATTORNEY	:
FIRM:	
PAGES, INCLUDIN	G COVERSHEET:
PHONE NUMBER:	
TO EXAMINER:	P. Ponnaluri
ART UNIT:	1639
SERIAL NUMBER:	09/963,920
FAX/TELECOPIER	NUMBER: (703) 308-4315
PLEASE NOTE:	THIS FACSIMILE NUMBER IS TO BE USED ONLY FOR RESPONSES TO RESTRICTIONS.
COMMENTS:	

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

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